EXHIBIT 58

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax:(973) 526-6069	01/10/2006 - 02/08/2006* FEI NUMBER 2244683

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Divya C. Patel, President

FIRM NAME	STREET ADDRESS
Amide Pharmaceutical, Inc	101 East Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Little Falls, NJ 07424-5608	Pharmaceutical Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The following observations relate to coverage of the Postmarketing Adverse Drug Experience Reporting System:

OBSERVATION 1

Adverse drug experience information has not been reported to FDA.

Specifically, the following adverse drug experiences or information regarding serious, unexpected adverse drug experiences were not submitted to FDA.

(a) Unsubmitted serious, unexpected 15-day alert experiences, where Amide (the application holder or reponsible party) did not submit to FDA, e.g.:

MRN	*Date Rcvd by Affr*	*Suspect Amide Drug*	*Adverse Experiences*
[redacted]	12/17/1999	[redacted]	Primary pulmonary hypertension, Valvular heart disease (regurgitation), Neurotoxic injuries (NOS) (neurotoxological disorder)
02-006	5/3/2002	Digitek (digoxin) Tablets	Congestive cardiac failure, Cataract extraction, Visual disturbance NOS, Fatigue, Weakness, Anorexia, Weight Decreased
03-017	3/28/2003	Digitek (digoxin) Tablets 0.25mg	Generalized weakness, Atrial fibrillation, Feeling of semi-consciousness, Possible digoxin toxicity
[redacted]	7/23/2004	[redacted]	Asthenia, Feeling abnormal, Headache, Chest discomfort, Nausea, Feeling jittery, Oedema peripheral, Hypersensitivity, Rash
[redacted]	1/21/2005	[redacted]	Panic attack, Anxiety, Chemical imbalance, Comatose for six months, Lost memory
[redacted]	10/5/2005	[redacted]	Death from cardiac dysrhythmia, Overdose

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DEFENDANT'S EXHIBIT 5888

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(b) Unreported or inaccurate information from serious, unexpected 15-day alert reports, as documented on telephone records or in forwarded case information from a contracted affiliate, e.g.:

MRN	*Date Rcvd by Mfr*	*Suspect Amide Drug*	*Adverse Events*
00-015	5/9/2000	Digitek Tablets (digoxin) 0.25mg / ANDA 40-282	Death in 2.5 hours after ingestion of first tablet
o	Unreported Information: Previous Condition - Diabetic		
01-020	9/7/2001	Digitek (digoxin) 0.125g Tablets / ANDA 40-282	Feet swelling
o	Unreported Information: Event reappeared after reintroduction of medication, dehydration, low potassium level, arrythmia		
[redacted]	9/29/2005	[redacted]	Dizziness, Hallucination, Fall resulting in 3 broken toes and bruised ribs, Overdose, Lack of effect
o	Unreported Information: Incorrect concomitant medication [redacted] Additional suspect medications were identified by the reporter but not listed as suspect medications on the MedWatch Form 3500A, Provided dosages of concomitant medications were not listed, Narrative incorrect in that broken ribs were listed although broken toes were reported, Narrative was summarized and not complete		

(c) Unreported follow-up information from the patient's doctor regarding the following serious, unexpected adverse drug experience:

MRN	*Initial Date Rcvd by Mfr*	*Follow-up Information Date Rcvd by Mfr*	*Suspect Amide Drug*	*Adverse Events*	*Follow-up information reported by Physician*
00-015	5/9/2000	7/24/2000	Digitek Tablets (digoxin) 0.25mg	Death in 2.5 hours after ingestion of first tablet	Allergic to codeine, Cause of Death: Arrest

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OBSERVATION 2

Adverse drug experiences that were the subject of post marketing 15-day reports were not investigated.

Specifically, there were no follow-up investigations for the following serious, unexpected experiences:

MRN	*Date Rcvd by Mfr*	*Suspect Amide Drug*	*Adverse Experiences*	*Submitted to FDA*	*Expected Follow-up*
01-020	9/7/2001	Digitek (digoxin) Tablets 0.125mg	Swollen feet	Yes	Determine resolution of experience, as patient's experience had not resolved at the time of reporting.
02-006	5/3/2002	Digitek (digoxin) Tablets	Congestive cardiac failure, Cataract extraction, Visual disturbance NOS, Fatigue, Weakness, Anorexia, Weight decreased	No	Determine resolution of experiences, as patient's experiences had not resolved at the time of reporting.
[redacted]	10/5/2005	[redacted]	Death from cardiac dysrhythmia, Overdose	No	Determine patient history, concomitant medications, laboratory tests, indication for use

OBSERVATION 3

Adverse drug experience information obtained or otherwise received from any source was not reviewed, including information from commercial marketing experience and reports in the scientific literature.

Specifically, incoming adverse drug experiences from spontaneous, clinical trials, and scientific literature are often not reviewed for seriousness and/or expectedness. Any adverse experience which the firm submits to FDA is submitted as a 15-day expedited report.

Additionally, the firm receives published literature on a monthly basis for review, but does not capture serious, unexpected experiences for cases requiring 15-day expedited reports, per Departmental Operating Instructions RA-009, Adverse Drug Experiences (ADE) Reporting to FDA, effective 7/20/2002.

OBSERVATION 4

Individual ADEs which were not reported to FDA in a post marketing 15-day alert have not been included in a periodic safety report.

Specifically, the firm has never filed a periodic report with FDA. ANDA and NDA approval dates range from 2/28/1997 to

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10/24/2005. The firm's procedure, Departmental Operating Instructions RA-009, Adverse Drug Experiences (ADE) Reporting to FDA, effective 7/20/2002, requires the submission of periodic reports. Several adverse experiences remained unreported, e.g.:

MRN	*Date Rcvd by Mfr*	*Suspect Amide Drug / ANDA*	*Adverse Events*	*Seriousness / Expectedness*
03-011	3/17/2003	Digitek (digoxin) Tablets 0.125mg / ANDA 40-282	Unresolved loss of taste	Non-serious / Unexpected
[redacted]	10/21/2003	[redacted]	Tremors, Severe nervousness	Non-serious / Expected
04-002	1/23/2004	Digitek (digoxin) Tablets 0.125mg / ANDA 40-282	Frequent bowel movements, Fatigue, Lightheadedness, Paleness, Abnormal feeling	Non-serious / Unexpected
04-038	8/6/2004	Digitek (digoxin) Tablets 0.25mg / ANDA 40-282	Appetite decreased, Weight loss, Tiredness, Tremors	Non-serious / Unexpected
[redacted]	8/10/2004	[redacted]	Drug didn't show up in blood test, Insomnia	Non-serious / Unexpected
04-042	8/18/2004	Digitek (digoxin) Tablets 0.25mg) / ANDA 40-282	Black tooth deposits	Non-serious / Unexpected
04-053	9/20/2004	Digitek (digoxin) Tablets 0.125mg / ANDA 40-282	Nausea, Vomiting, Confusion, Heart block	Non-serious / Expected
[redacted]	5/2/2005	[redacted]	Chest pain, Increased blood pressure, Lack of effect	Non-serious / Unexpected
[redacted]	11/18/2005	[redacted]	Unresolved dry cough	Non-serious / Expected

Further, 17 periodic adverse experiences reported by one nurse in September 2000 were not submitted for atrial fibrillation and lack of effect when taking Digitek (digoxin) Tablets. The nurse reported that 20 patients were switched to the innovator brand and his/her adverse experiences resolved within three weeks; only 3 reports were submitted.

OBSERVATION 5

Written procedures have not been developed for the evaluation and reporting to FDA of post marketing adverse drug experiences.

Specifically:

(a) There is no procedure regarding the initiation of follow-up investigations for serious, unexpected adverse experiences.

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(b) There is no procedure to adequately complete the MedWatch Form 3500A in that the firm never completes Adverse Event Terms, Section G8.

(c) There is no procedure for the maintenance of records to assure timely submission of 15-day alert reports to FDA.

(d) There is no procedure for a review of MedWatch Forms to assure the accuracy of information reported to FDA. The firm does not conduct reviews of the cases prior to submission, e.g. information in the 'Describe event or problem', Section B5, was often incomplete and 'Date received by manufacturer', Section G4, was often inaccurate.

The following observations relate to coverage of Good Manufacturing Practices:

Quality System

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been thoroughly distributed.

Specifically:

(a) The firm failed to investigate thirteen consumer complaints for [redacted] breakages, nine received 2/27/2004 - 7/16/2004 and four received 2/9/2005 - 5/17/2005. Four total complaints were received for lot [redacted] (2/27/2004, 6/15/2004, 6/29/2004, 5/17/2005). No evaluation of the decision and impact on previous batches was conducted regarding a change from red opaque/white opaque capsule shells to white opaque/white opaque capsule shells. The capsule shells were changed upon advice from the capsule shell manufacturer to prevent breakage.

Further, although a change control request was approved on 7/27/2004 approving the use of white opaque/white opaque capsules, the firm continued to use the red opaque/white opaque capsules in three additional batches (7/29/2004, batch 4360A; 8/6/2004, batch 4397A; 8/9/2004, 4398A) until the supply was exhausted.

(b) The firm failed to thoroughly investigate an intact metal screw found in a bottle of [redacted] as reported in Consumer Complaint [redacted] dated 12/5/2004. Although the complaint investigation determined that the screw was from an Amide packaging machine, no additional investigation was conducted.

(c) The firm failed to investigate an out-of-specification percent yield for bulk [redacted] on 12/27/2005.

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OBSERVATION 7

Complaint procedures are deficient in that they do not include provisions that allow for the review and determination of an investigation by the quality control unit.

Specifically, the firm's complaint handling procedure does not cover the initiation of a formal investigation when necessary, such as multiple complaints for the same lot of product or confirmed contamination complaints. For example, investigations were not conducted when four complaints were received for cracked [redacted] or for an intact metal screw, confirmed to be from the firm's packaging equipment, found in a bottle of [redacted]

OBSERVATION 8

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, the qualification and start-up procedures are inadequate for the [redacted] in that the equipment was not challenged prior to the inspection to assure accuracy, per the equipment manual. [redacted] is a 100% capsule weight sorter used to separate low and high weight [redacted] and was qualified on 12/1/2005. Challenge tests conducted during the inspection failed to reject all out-of-specification capsules.

Regarding the manual encapsulation process, the in-process testing was not evaluated after implementation of [redacted] resulted in additional rejects. The in-process testing involves weighing 10 individual capsules every two hours and one group of 10 capsules every 30 minutes. [redacted] rejects have accounted for approximately 1-3% of overall product yield for each of the nine lots which used [redacted] an out-of-specification product yield for [redacted]. The firm has not evaluated the adequacy of the in-process testing, which potentially impacts the capsules released not using [redacted] and the adequacy of the manual encapsulation manufacturing process.

* DATES OF INSPECTION:
01/10/2006(Tue), 01/11/2006(Wed), 01/12/2006(Thu), 01/23/2006(Mon), 01/24/2006(Tue), 01/25/2006(Wed), 02/06/2006(Mon), 02/08/2006(Wed)

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FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Tara R. Gooen

Tara R. Gooen, Investigator

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